Phthalates in Medicinal Products, with Katherine Kelley

Ashley Ahearn

Americans are widely exposed to phthalates in soft plastic products from toys to medical equipment. A perhaps lesser-known potential source of exposure is the timed-release coatings on certain pharmaceuticals and dietary supplements, which enable active ingredients to reach the correct part of the gastrointestinal tract for working properly. In this podcast, host Ashley Ahearn talks to Katherine Kelley about her new study on the extent to which phthalates are used in medicinal products.

AHEARN: It's *The Researcher's Perspective*. I'm Ashley Ahearn.

Americans are widely exposed to phthalates, some of which have been identified as being harmful to development and reproductive health in animals and humans.[1]

You'll find phthalates in a wide variety of soft plastic products—from rubber duckies and other kids' toys to vinyl tubing and medical equipment.

And here's another potential source of exposure: the coating for timed-release pharmaceuticals and dietary supplements. That's according to a 2009 paper published in *EHP*.[2]

In a new study, investigators looked at how widely phthalates are used in medicinal products.[3] Joining me to talk about it is Katherine Kelley. She's a research pharmacist at the Slone Epidemiology Center at Boston University and a lead author on the new paper.

Hi, Kathy.

KELLEY: Hi, Ashley.

AHEARN: So, phthalates—what kind of capabilities do they provide that make them a good thing to put into medical products?

KELLEY: They allow for the timed release or targeted release of specific medications, so they're important in formulations that require those specific capabilities—so, say, targeted release of a medication to a specific part of the GI tract, like to the colon for treatment of colitis. Other times it can be important to protect the GI tract from irritating substances like aspirin, or the stomach from laxatives where you don't want them to dissolve; you want those to dissolve in the intestine where they can provide the stimulant action. In supplements, it's more to protect the contents of the product—say, something like probiotics, where you want the bacteria to be available in the intestine, not in the stomach, or enzymes where you don't want them to break down too soon so that they can exert their actions properly.

AHEARN: So if I take a timed-release pain relief medication, you know, over the counter, I could be exposing myself to phthalates?

KELLEY: Potentially, but it can vary based on the manufacturing characteristics of that particular product, so you really have to look at the drug facts labeling and read it carefully to see if it does contain any phthalate.

AHEARN: But it may not be labeled for phthalates specifically, is that right?

KELLEY: No, over-the-counter drugs generally contain a full disclosure of ingredients. What I found was in prescription drug products, because of the proprietary nature of the drug formulations, they're permitted to put limited information and not fully disclose all of the information about the ingredients if they're under patent protection. So they could say that it contains "other ingredients" and not fully disclose all of the elements of the coating system for that particular drug.

AHEARN: Kathy, how does the exposure from medicinal products compare to just that daily exposure. Is it less? Is it more?

KELLEY: From the studies that have been done of exposure to medications in humans—and there have been a handful of studies—the exposure level can be 2–3 orders of magnitude greater, so it would 100–1,000 times greater from the orally ingested products versus the other background exposure.

AHEARN: So what do we know about how phthalates affect human health, overall?

KELLEY: We have limited information on the effect of phthalates on human health. In a number a different animal studies, there have been shown to be a constellation of male

reproductive tract anomalies called phthalate syndrome, but it hasn't been reproduced in humans per se yet.

AHEARN: And are there alternatives to using phthalates in these coatings and medical products like that?

KELLEY: Yes, there are alternatives, and so within a particular type of product, whether it's aspirin or fish oil or garlic or a prescription drug like mesalamine, there are sometimes alternative formulations that are on the market. So within that product active ingredient range you may have choices for products that do not contain phthalates. So it's good to look for alternatives where they exist.

AHEARN: Kathy, what turned you on to this area of research? What fascinates you about phthalates and this type of exposure specifically?

KELLEY: I find it very interesting from a drug safety and regulatory perspective that these compounds are allowed to be included in drug formulations. It may be that they're safe, but we just at this point feel that there may not be enough information in human data to show that they should be permitted to be continued to be used in these products. So I find that interesting from a regulatory perspective and a drug safety perspective.

AHEARN: And what questions do you hope to focus on next in your research or do you see needing to be answered in your field about these substances?

KELLEY: Our research group here will be continuing to study the effects of phthalates using a case–control surveillance study here at the Slone Epidemiology Center, our Birth Defects Study.[4] And now that we have defined some possible exposure to phthalates from these medications, we hope to examine that effect in pregnant women within our study and look for potential male genital tract malformations such as hypospadias and cryptorchidism, which is undescended testicles.

AHEARN: How do you hope your research is used in forming public policy or maybe regulatory decisions going forward?

KELLEY: I would hope that it would answer questions about the safety of the use of these compounds in medicinal products. I don't think that there's enough information to make regulatory decisions at this time, so I hope that it contributes to the body of evidence that's available so that decisions can be made about their relative safe use.

AHEARN: Kathy, thanks so much for joining me.

KELLEY: Thank you.

AHEARN: Katherine Kelley is a research pharmacist at the Slone Epidemiology Center at Boston University.

And that's *The Researcher's Perspective*. I'm Ashley Ahearn. Thanks for downloading!

Ashley Ahearn, host of *The Researcher's Perspective*, has been a producer and reporter for National Public Radio and an Annenberg Fellow at the University of Southern California specializing in science journalism.

References

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